DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HFI-35 5145

60 8th Street, N.E.
Atlanta, Georgia 30309

January 23, 2001

VIA FEDERAL EXPRESS

WARNING LETTER
(01-ATL-24)

Ole C. Krarup, President
Dixie Health, Inc.
2161 Newmarket Parkway
Suite 222
Marietta, Georgia 30067

Dear Mr. Krarup:

This letter is in reference to your firm's marketing of the product labeled, "PROGESTONE 900." Labeling for this product contains therapeutic claims that cause the product to be a drug, under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The literature (labeling) for the product includes such claims as "Progestone 900 Dual Product for PMS & Menopause Relief Wanting Osteoporosis Protection?...easily absorbed into the skin and is designed for women who cannot produce enough Progesterone on their own. It is the only dual product on the market containing BOTH 900 mg. of pharmaceutical-grade Progesterone and 1,995 mg. of Dermasterone, a bioactive multi-species Wild Yam complex...Progestone-900 is recommended for Osteoporosis protection... recommended for...Headaches · Hot Flashes..." The immediate product container references this labeling with the statement, "Directions: Apply ¼ Teaspoon of Cremegel to Desired Areas, Morning and Night. See Product Literature for Further Details...".

The Dixie Health, Inc. pages stamped, "Educational Material Only" claims, "Progestone 900 USP CREMEGEL with WILD YAM ROOT EXTRACT GENERAL HEALTH BENEFITS...contains 900 mg. of USP progesterone,...easily absorbed through the skin, taken up by the fatty layer under the skin, and then transferred into the bloodstream where they are circulated throughout the body."..."rotate application sites to assure best absorption, using a different body site for each of four days, then repeating...Apply after bathing...To prevent any possible interference with absorption...PERI-MENOPAUSE/SEVERE PMS:...OSTEOPOROSIS...for prevention of osteoporosis, use 1 oz. per month, ...endometriosis:"

The article, titled "Wild Yams The Natural Choice for Female Hormones", accompanies the above described labeling. This article references the benefits of wild yam root as a spasmolytic, mild diaphoretic, anti-flammatory, anti-rheumatic and cholagogue for use in the treatment of Intestinal colic, Diverticulitis, Rheumatoid arthritis, Muscular rheumatism, Cramps, Intermittent claudication and Ovarian & uterine pain.

Therefore, Progestone is a new drug as described in Section 201(p) of the Act. This product may not be legally marketed in this country without an approved New Drug Application, Section 505(a) of the Act. It is also misbranded under Section 502(a) of the Act because its labeling is false and misleading since it suggests that this drug is safe and effective for its intended uses, when, in fact, this has not been established. This drug is further misbranded under Section 502(f)(1) of the Act because its labeling fails to bear adequate directions for its intended uses.

In addition, this product is transdermal and is intended to deliver active ingredients directly into the bloodstream. Transdermal delivery systems are new drugs based on the newness of the delivery system, Title 21, Code of Federal Regulations (21 CFR), Section 310.3.

Further, topical hormone creams are addressed in an Over-the-Counter Drug, Final Monograph, titled Topically Applied Hormone-Containing Drug Products, published in the Federal Register on September 9, 1993, and became effective March 9, 1994. The monograph is included in 21 CFR, Section 310.530 (copy enclosed). Any over-the-counter (OTC) drug product labeled, represented, or promoted as a topically applied hormone-containing product for drug use (with the exception of hydrocortisone and hydrocortisone acetate) is regarded as a new drug. These products may not be introduced into interstate commerce unless they are the subject of an approved new drug application (NDA).

We have also noted that the Dixie Health web page makes a variety of claims for this product. The claims include: "... WITH 900 mg. USP NATURAL PROGESTERONE ... PMS & Menopause Relief & Osteoporosis Protection ... It is for women who are clinically deficient in progesterone. The 900 is recommended for women who do not ovulate or who had their ovaries removed, and all women with osteopenia or osteoporosis issues ... relieve severe PMS and Menopausal symptoms..." The claims that appear on your web site represent or suggest that this product is intended to be used in the cure, mitigation, treatment, or prevention of disease and may further misbrand the product.

We request that you notify this office in writing within fifteen (15) working days of receipt of this letter, stating the action you will take to discontinue the marketing of this drug product or to otherwise bring it into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

This letter does not represent a comprehensive review of all of the products distributed by your firm. It also does not represent a complete review of all product labeling or promotional materials, including any Internet web sites, you may use. As the most responsible individual at the firm, it is your responsibility to ensure that all products marketed by your firm meet the requirements of the Act and its implementing regulations.

Your reply should be directed to the attention of Philip S. Campbell, Compliance Officer, at the address noted in the letterhead. Mr. Campbell can be reached at (404) 253-1280 to discuss the contents of this letter or if you have questions about the promotion of your other products.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosure